

REMARKS

I. Status of the Claims

Claims 1-8 and 10-24 are pending. The limitations of claim 9 have been incorporated into independent claim 1, and claim 9 has been cancelled. A similar limitation defining a Markush group of oral comfort ingredients has been introduced into claims 17 and 24. The claims are believed to be in condition for allowance and reconsideration is respectfully requested.

In the June 30, 2003 Office Action, arguments previously presented in the Request For Continued Examination (RCE), in an interview with the Examiner, and in an Amendment filed before the RCE, were disregarded by the Examiner as "moot," in favor of new grounds of rejection, as follows.

Claims 1-16 and 23-24 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification as filed allegedly does not provide support for more than one salivation or oral comfort region.

Claims 1-6, 8-12, 17 and 22-24 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 407,019 (Cherukuri).

Claims 1-3, 6-10, 13, 15-17 and 22-24 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,306,429 (Bealin-Kelly).

Claims 17-18 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,231,900 (Hanke), which was applied in the previous Office Action.

Claims 20-21, directed to a treatment for xerostomia, have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cherukuri and U.S. Patent No. 4,983,378 (Parnell).

Claims 11 and 14 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bealin-Kelly.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hanke in view of U.S. Patent No. 6,099,880 (Klacik), both of which were applied in the last Office Action.

Before turning to these rejections on the merits, applicants note that the Hanke reference was discussed at length in the last Office Action. The Manual of Patent Examining Procedure (MPEP) § 707.07(f) requires that if the Examiner issues new grounds of rejection, she must still address any arguments presented by the applicant which are still relevant to any references being applied. In this case, the Examiner has ignored the remarks with respect to Hanke, specifically that Hanke does not disclose a segregation of oral comfort and salivation ingredients. Moreover, the Hanke reference is clearly related to the newly applied Bealin-Kelly reference (both references disclose a product containing discrete "cooling" and "warming" regions in a center-filled configuration). Applicants respectfully request that those arguments be addressed.

## II. Rejection Under 35 U.S.C. § 112, First Paragraph

With respect to the 35 U.S.C. § 112, first paragraph rejection, applicants respectfully traverse. Support for multiple regions can be found at least at page 10, line 21

of the specification, which refers to "multiple salivation and oral comfort regions," and at page 16, lines 16-32, which discloses "at least two separate and distinct regions."

Applicants submit that there is clear support for the claim language "one or more."

### III. Rejections Under 35 U.S.C. § 102

Turning to the rejections over prior art, all of the claims, as amended, require an oral comfort ingredient selected from proteins, surfactants, lipids and mixtures thereof. The prior art does not disclose a product which has a salivation agent in one discrete region of the product, and a protein, surfactant and/or lipid in a separate region of the product which performs an oral comfort function.

The key feature of the present claims that has not really been addressed, even in the "new" rejections is the product configuration: that the salivation agent is concentrated in a discrete and separate region of the product such that salivation is enhanced; and an oral comfort ingredient is provided in another region. While an acidulant evenly distributed throughout a product may cause a certain amount of salivation, the effect is enhanced if the same amount of acidulant is provided in discrete pockets, for reasons unrelated to the overall concentration of salivation agent in the product. This is because a high concentration of acidulant in isolated pockets increases the "punch" of the acidulant in that localized area, causing oral manipulation of the candy in the mouth. For example, a given amount of acid which might make a confection "tart" if it is distributed throughout the product, if it is concentrated in discrete regions causes a much more tart, even irritating, sensation in those regions. This causes mechanical motion of the piece in the mouth,

increasing salivation. Of course, without an oral comfort region, the high localized concentration of acid in the salivation regions would not be well tolerated. Thus, the invention does not reside so much in the discovery of an individual salivation agent, or a level of an agent that yields a certain salivation effect, but in a product configuration that enhances a salivation effect.

With respect to the 35 U.S.C. § 102 rejection over Cherukuri, it is not clear from the Office Action what regions are considered to read on the claimed salivation region and what regions are considered to read on the claimed oral comfort region, or why the recited ingredients are considered to perform the claimed functions.

However, in embodiments, Cherkuri discloses a center filled chewing gum (see Cherukuri, page 5, lines 40-45). The gum base and the center are understood to be the discrete regions. The gum base is said to contain a hydrophilic polymer in an anhydrous carrier which has a saliva stimulating effect (see page 6, lines 21-23). See also page 12, lines 42-48 of Cherukuri, which show that the gum contains salivation agents. Thus, the gum base would appear to be what the Examiner considers a salivation region. However, the Office Action seems to imply that hydrogenated vegetable oil/animal fat, monoglycerides and emulsifiers in the gum base are oral comfort ingredients; but as noted above, these ingredients are in the gum base, contrary to the claimed invention. Moreover, the hydrogenated vegetable oil is homogeneously distributed in the base, and not stated to have an oral comfort effect.

Bealin-Kelly discloses a confection having a discrete warming region and cooling region. Again, it is not clear exactly how these regions are alleged to correspond to salivation and/or oral comfort regions. The composition of the respective regions is set forth broadly in claim 1 of Bealin Kelly and at page 3 of the Office Action. However, nothing in this patent shows an oral comfort region comprising a surfactant, lipid or protein.

The Office Action suggests that the presence of the emulsifier (lecithin) in amounts of 0.02 percent by weight in the center fill material is sufficient to read on the claimed oral comfort ingredient. However, no oral comfort effect for lecithin is described in the disclosure, and none would be expected. To the contrary, the presence of lecithin is simply to homogeneously distribute the ingredients of the liquid filling. See Bealin-Kelly, col. 4, line 64 to col. 5, line 19.

With respect to Hanke, the same remarks that apply to Bealin-Kelly apply to the Hanke reference. Specifically, this reference teaches the segregation of cooling and warming compositions in a center filled chewing gum. The reference does not teach that an oral comfort ingredient comprising a surfactant, protein or lipid may be provided in a separate region from a salivation region to provide sensory contrast from the salivation region.

For at least the foregoing reasons, applicants submit that none of Cherukuri, Bealin-Kelly or Hanke anticipates the pending claims.

IV. Rejections Under 35 U.S.C. § 103(a)

In the Office Action, U.S. Patent No. 4,983,378 (Parnell) is combined with Cherukuri against claims 20-21, alleged to make obvious the method of treating xerostomia with the subject composition. Cherukuri alone appears to suggest treatment of xerostomia (see page 6, line 23). However, the issue is that the combination of Cherukuri and Parnell does not teach or suggest the segregation of oral comfort and salivation components as set forth in the claims. Parnell does not overcome the deficiencies of Cherukuri in this respect.

Parnell is said to teach including an acid in a center fill region. This is alleged to suggest including a salivation agent in a center fill region of the Cherukuri product. Even if that combination were obvious, the resulting product would not have an oral comfort ingredient selected from surfactants, lipids, proteins or mixtures thereof in a discrete region, because as noted above, the gum base in Cherukuri causes or promotes salivation.

Critically important with respect to the amended claims, the Office Action argues that claims 11 and 14 are obvious in view of Bealin-Kelly alone, because lecithin (an emulsifier which has surfactant properties) is alleged to be useful in amounts of 0.001 to 1 percent by weight. However, there is no disclosure in Bealin-Kelly that the lecithin is an oral comfort ingredient. The lecithin encapsulates the cooling or warming agent and thereby serves to distribute the agent in the center filling (in amounts of 0.02 percent by weight). Thus, there is no disclosure of a surfactant-, lipid- or protein-containing oral

comfort ingredient or separate oral comfort region. Nor is there any suggestion in Bealin-Kelly to provide oral comfort ingredients in one or more oral comfort regions.

It was emphasized in the previous response, and in conversations with the Examiner, that the product functionality is considered critical to the novelty of the claimed invention. Specifically, the ingredients of the oral comfort region are set forth as a Markush group: surfactant, protein and lipid. Of course, this group covers many different ingredients, and it may be possible to find one such ingredient in a discrete region of an edible product. However, the prior art references of record do not teach or suggest the presence of these ingredients as oral comfort agents in a discrete region segregated from a salivation ingredient.

As applicants have noted in the prosecution of this application, Federal Circuit case law requires that functional limitations in the claims be considered. See, e.g., *In re Swinehart*, 439 F.2d 210 (CCPA 1971); *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997) (“A patent applicant is free to recite features of an apparatus either structurally or functionally); *In re Venezia*, 530 F.2d 956 (CCPA 1976); *Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc.*, 607 F.2d 885 (10th Cir. 1979), *cert. denied*, 444 U.S. 1018 (1980), on remand, 515 F. Supp 834 (W.D. Okla. 1980), *aff’d in part, reversed in part*, 708 F.2d 1554 (10th Cir. 1983) (“the idea that functional language *ipso facto* cannot precisely define novelty in structure was laid to rest in *In re Swinehart*. . .”). Therefore applicants again request that the functional features of the claimed edible product, be given consideration in determining the allowability of the present claims.

Finally, with respect to the rejection for alleged obviousness of claim 19 over Hanke in view of U.S. Patent No. 6,099,880 (Klacik), applicants cannot find in Klacik the disclosure of a mold having a ridge, as alleged in the Office Action. Moreover, as with the rejections traversed above, no combination of Hanke and Klacik shows a segregation of oral comfort ingredient from salivation ingredient in discrete regions as set forth in the claims.

#### CONCLUSION

In view of the foregoing amendment and remarks, applicants submit that the present claims are patentable over the cited references and respectfully request allowance and prompt passage of the application to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address given below.

Respectfully submitted,

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